

(21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 22, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97-13535 Filed 5-21-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting for Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. This meeting will provide participants an opportunity to hear a discussion on prescription (Rx) to over-the-counter (OTC) switches and the new OTC proposed labeling initiative.

DATES: The meeting will be held on Thursday, May 29, 1997, from 1:30 p.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the Bethesda Holiday Inn, 8210 Wisconsin Ave., Bethesda, MD. Interested persons may register with Betty Palsgrove at 301-443-1652. Registrations also may be transmitted by FAX to 1-800-344-3332 or 301-443-2446.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5470.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff and to provide an opportunity for informal discussion on the switching of drug products from prescription to OTC status and on FDA's proposed regulation for labeling of OTC drug products, which would amend 21 CFR parts 201, 330, and 358 (62 FR 9024, February 27, 1997).

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person listed above. Registration

should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: May 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-13447 Filed 5-21-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Science Advisory Board to the National Center for Toxicological Research

Date, time, and place. June 5 and 6, 1997, 9 a.m., Bldg. 12, conference room, National Center for Toxicological Research, Jefferson, AR.

Type of meeting and contact person. Open board discussion, June 5, 1997, 9 a.m. to 4:30 p.m.; open board discussion, June 6, 1997, 9 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not

last that long; closed board deliberations, 12 m. to 1:30 p.m.; Ronald F. Coene, National Center for Toxicological Research (HFT-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3155, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Science Advisory Board to the National Center for Toxicological Research, code 12559. Please call the hotline for information concerning any possible changes.

General function of the board. The board advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs to fulfill regulatory responsibilities.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 26, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open board discussion. The board will be presented with draft reports, for review and discussion, from two site visit review teams: (1) On the Estrogen Knowledge Base Program, and (2) on the Information Management Program. Staff from the Analytical Methods Program will provide a progress report on the recommendations made by the Science Advisory Board. Also there will be discussion of an agenda for future program review site visits, an update from the Director, and a review of the progress the agency has made in establishing the Arkansas Regional Laboratory at the Jefferson, AR site.

A final agenda will be available on June 3, 1997, from the contact person.

Closed board deliberations. The board will discuss personal information concerning individuals associated with the research programs at the center, disclosure of which would constitute a clearly unwarranted invasion of personal privacy. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Each public advisory committee meeting listed above may have as many